DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

9122d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-52

April 16, 2001

FACILITY ID # 217661

Diana Cobo, Mammographer
IMI of Miami
7800 S.W. 87th Avenue
Suite A-110
Miami, Fl 33173

Dear Ms. Cobo:

A representative of the State of Florida acting in behalf of the Food and Drug Administration (FDA) inspected your facility on February 22, 2001. This inspection revealed serious regulatory problems involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and 2 findings at your facility:

Level 1

- Quality Control phantom records were missing for 11 weeks.

Level 2

- The fixer retention records were not done for the processor at the facility. The screen film contact was not done at the required frequency.

The specific deficiencies noted above appeared on the List of Observations which was issued to your facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. The actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging

your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

We acknowledge receipt of a letter dated January 22, 2001, signed by Dr. Germaine Rosensweig advising that your facility has decided to stop performing mammography as of January 6, 2001. It is not necessary for you to submit an additional response to this letter at this time.

You should not display your facility certificate since it has expired. If FDA establishes that your facility continued to perform mammography without a valid certificate, you could be subject to sanctions under MQSA.

Finally, you should understand that there are many FDA requirements pertaining to mammography. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or on the internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements or about the content of this letter, please feel free to contact D. Janneth Caycedo, Consumer Safety Officer, FDA's Boca Raton Resident Post, at (561) 338-5236, ext. 23.

Any future replies should be directed to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma R. Singleton
Director, Florida District